DECLARATION UNDER 37 C.F.R. § 1.132 OF VERONICA TOWNSEND (ROBINSON)		
	Application #	09/341,299
	Confirmation #	4968
	Filing Date	31 August 1999
	First Inventor	ROBINSON
	Art Unit	1616
	Examiner	Levy
	Docket #	P06407US00/BAS

I, Veronica Townsend (Robinson), declare and state as follows:

1. I am the inventor of the above-identified patent application, and in addition, I run a company known as Lice Busters, International Pty Ltd of Cannington Australia which has marketed and sold products of the type embodied in the claims of the present patent. I am thus very familiar with the development and advantages of the present invention as well as its marketing and sales over the past few years.

2. As an initial matter, it is my understanding that the Examiner in the above case has raised questions with regard to the potential toxicity of pyrethrum, one of the insect repellant agents used in the present invention. Such a position is not correct in light of the fact that pyrethrum has been subject to extensive testing over the years and is considered a safe and effective non-toxic insecticide. As pointed out in the article attached hereto ("Pyrethrum: A Safe and Effective Natural Insecticide"), this material has been subject to a 10-year safety test of the US EPA which showed that, through the use of state-of-the-art procedures, that "pyrethrum extract has a low order of toxicity and is unlikely to cause skin and eye irritation or sensitization." Accordingly, pyrethrum has been proven safe and non-toxic.

3. I have also reviewed the Examiner's comments in the Official Action in the above application, particularly with regard to the cited prior art reference of Page, US Patent 246,335, issued August 30, 1881. This reference only discloses a garment which is directly coated with paraffin wax and which would be entirely unsuitable as a garment which a consumer would want to purchase or wear. In addition to being extremely unattractive to have a garment containing a waxy and messy coat of paraffin, having a waxy coat on the outside of the garment will result in having pieces of wax fall off as the user is wearing the garment, which is not only unattractive and undesirable, it may also result in harmful paraffin wax falling into one's food or one's eye. The very old Page US patent that the Examiner cited thus has never been the model for a saleable product with good reason – it is totally unattractive and unworkable and as a result would never be purchased by a consumer looking for a garment to wear and provide insect protection at the same time.

4. In total contradiction to the waxy and messy coated materials of the Page patent, my claimed invention relates to particular inserts which act as repellants for lice and other harmful parasitic insects, and which go on the <u>inside</u> of a garment so as to maintain the garment itself as attractive and saleable. Accordingly, my claimed invention is a huge advance over the Page product, and provides for the first time a saleable attractive product which also performs the function of providing safe and effective insect repellant properties which are controllably released based on the body temperature of the wearer of the product.

5. By virtue of the attractiveness and advantages provided by my claimed invention, products embodying the invention have been a huge commercial success. Starting without the backing from a large company for development and advertising, sales of the Lice Buster products embodying the invention have been very good, and reached a maximum of about $1 million per year. Accordingly, it is clear that my invention has been a commercial success. It is my full expectation that such sales will continue to rise over the coming years.

I hereby state that all statements made herein based on my own personal knowledge are true and correct and that all statements based on my information and belief are true and correct to the best of my knowledge, and further that all of these statements have been made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

23rd June 2004
Date

Veronica Townsend (Robinson)

Pyrethrum

A Safe and Effective Natural Insecticide

Interest is growing for this naturally-derived insecticide due to its unique properties and safety profile. Pyrethrum production is expected to significantly increase during the next five years.

By George R. Whalley
EUROPEAN EDITOR AND CONSULTANT

PYRETHRUM IS AN INSECTICIDE which is obtained from dried, daisy-like flowers of the *Chrysanthemum cinerariaefolium*, whose active components are known collectively as pyrethrins. The insecticidal use of pyrethrum flowers probably originated in Persia and Dalmatia, with its introduction into Europe and the U.S. during the latter part of the 19th century.

The flowers are commercially grown in various tropical countries, particularly Kenya, India, Papua New Guinea and Australia. Kenya is the largest supplier in the world. Pyrethrum production is expected to significantly increase during the next five years due to its proven effectiveness and safety record and also consumer preference for natural products.

Pyrethrum is a contact insecticide with a very good human and animal safety record. It is generally recognized to be one of the least toxic of all the natural domestic insecticides. It boasts a rapid knockdown effect and has broad spectrum activity against many insects because its active constituents contain more than one molecular species. The knockdown effect and killing power of pyrethrins and the synthetic pyrethoids are due to their ability to interfere with the insect's nervous system.

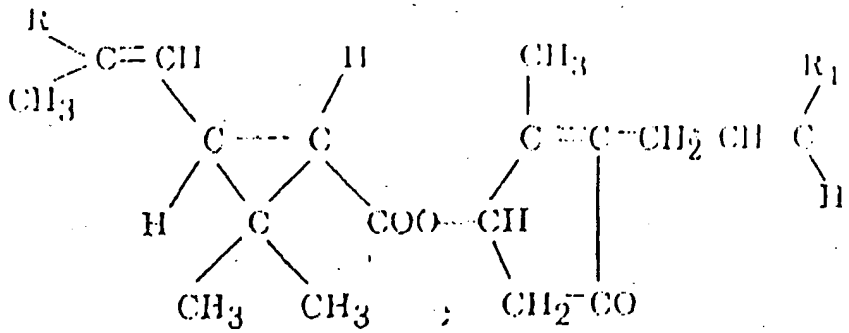
Pyrethrum is readily degraded by exposure to air and sunlight, so it is not subject to the problems of persistency so often exhibited by many other commercial insecticides. These and other attributes have led to the widespread use of pyrethrum insecticides for various household, agricultural and industrial purposes.

Pyrethrins Production

The active plant constituents are called pyrethrins. Actives are distributed throughout the whole plant, with the greatest concentration located in the flower head. Flowers are harvested at a stage when the petals are essentially horizontal, since this is when the maximum pyrethrins concentration occurs. Harvested flower heads are then sun or machine dried to a water content of about 10%. The powdered flowers are extracted with a light, aliphatic solvent. The solvent is subsequently "flashed off" to produce a dark, oleo-resin concentrate containing about 30% of the active material. The crude concentrate is usually further diluted and standardized to produce an oleo resin extract that contains 20-25% of active pyrethrins. Such extracts may contain additional materials such as sesquiterpenes, flavonoids, triterpinols, sterols, n-alkanes, carotenoids and various fatty acids.

Refined, de-waxed and de-colorized extract concentrates are also commercially available. A high-active, refined pyrethrum concentrate, containing 50-60% pyrethrins is available as well. The addition of an antioxidant such as butylated hydroxytoluene (BHT) is usually added to the extracts to prevent oxidation. New extraction methods are currently being investigated. One method uses carbon dioxide in a

Structural Formulas of Pyrethrins



where:

Pyrethrin I	R_1 is $CH{:}CH_2$	R is CH_3
Pyrethrin II	R_1 is $CH{:}CH_2$	R is $COO\,CH_3$
Cinerin I	R_1 is CH_3	R is CH_3
Cinerin II	R_1 is CH_3	R is $COO\,CH_3$
Jasmolin I	R_1 is $CH_2\,CH_3$	R is CH_3
Jasmolin II	R_1 is $CH_2\,CH_3$	R is $COO\,CH_3$

...to reduce the exposure of th... ...ray to level during solvent ...val. Relatively smaller quanti... of finely powdered pyrethrum ...ers are also available for the pro...tion of insecticidal dusts and ...quito coils.

...tives and Synergists

...ll insecticidal pyrethrins found in ...ethrum extracts are esters. They formed by the reaction of two ...ds, chrysanthemic acid and ...ethric acid, with three alcohols: ...ethrolone, cinerolone and jas...lone. The chrysanthemic acid ...rs are known as pyrethrin I, ...rin I and jasmolin I, known ...ectively as the Pyrethrins ...tion I and esters of pyrethric ...s, Pyrethrin II, cinerin II and ...molin II, are known as the ...thrins fraction II. These six ...pounds and their individual ...r configurations provide both ...insecticidal and knockdown ...ity of pyrethrum flowers and ... extracts.

...fferent growing conditions, ...ions and plant clones cause ...tions in the composition of the ...idual insecticidal pyrethrins. ...ver, within a particular loca... and over a significant time peri... the composition tends to be fairly ...tent. The ratio of pyrethrins I ...ethrins II is also maintained. ...s an important aspect, since the ...hrins II fraction has a greater ...k down effect than the ...thrins I fraction, which has ...r killing power.

...ynergist is an essentially non... ...terial that, when added to an ...cide, significantly increases its ...power. Its effectiveness is usu... ...xpressed as the ratio of the ...of the insecticide to that of the ...insecticide and synergist. ...ynergists used ...the s... include ...mono-...amolin, piperonyl butox...ide, tropital, bucarpolate, sesamex, safroxane, piperonyl cyclonene and sulfoxide. All of these compounds contain the methylene-dioxyphenol group in their molecular structure. Other effective synergists not containing this moiety include commercial preparations such as MGK 264, SKF 500 and octochlorodipropyl ether. Synergism is also exhibited by other insecticides, including the synthetic pyrethroids such as tetramethrin, resmethrin and allethrin.

Different growing conditions, locations and plant clones cause variations in the composition of the individual insecticidal pyrethrins.

Piperonyl butoxide, butyl-3, 4-methylenedioxy-6-propylbenzene-diethylene glycol ether, sulfoxide (1,2-methylenodioxy-4-[2-octylsulfynyl) propyl] benzene, tropital (piperonal *bis* [2-(2-n-butoxyethoxyethyl] acetal), and bucarpolate (ester of piperonylic acid and the mono-n-butyl ether of diethylene glycol) have all been used as pyrethrum synergists, as have commercial compounds such as MGK 264 and Synepirin 500. But today piperonyl butoxide and MGK 264 are the major synergists for both natural pyrethrins and the synthetic pyrethroids. These relatively inexpensive synergists have enabled for... ...pyrethrins ...products that cost less.

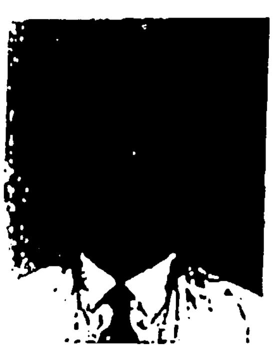
Synergists seem to inhibit the toxification of pyrethrins by the insect's own biochemical, self-protective mechanisms. Insects' ability to detoxify pyrethrins varies, so different quantities of synergist and pyrethrin are usually required for different insect species. Adult mosquitoes, for example, have a poor ability to destroy pyrethrins and therefore require a low level of insecticide and synergist. Houseflies, however, more readily destroy pyrethrins and consequently require higher dosage levels.

Safety and Toxicity

Throughout its widespread use, pyrethrum has generally been considered to be a safe insecticide. There is no clear evidence of any chronic poisoning in humans over many years of manufacture and use. Such general statements, widely accepted in the past, have been the subject of a 10-year safety investigation requested by the United States Environmental Protection Agency (EPA) for additional data to support the re-registration of all pesticides. Those concerned with the manufacture and use of pyrethrum products formed a consortium to obtain comprehensive data to meet EPA requirements. A natural pyrethrum extract, containing 57.6% of pyrethrins, having a pyrethrins I to pyrethrins II ratio of 1.58 was used as the reference sample.

The results of these studies, using state of the art procedures, indicate that pyrethrum extract has a low order of toxicity and is unlikely to cause skin and eye irritation or sensitization. It does not act as a teratogen or reproductive toxin and has a low potential to cause tumors in mammals. In fact, all the tests to date indicate and support earlier views that insecticides containing pyrethrum extracts present very few risks to humans or animals.

Ecotoxicological and environmental effects of pyrethrum have also been re-examined in light of the EPA requirements, and the results indicate that when correctly applied pyrethrum insecticides have little adverse effect on wildlife and no long-term adverse activity on the environment. Because of its rapid disappe...



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pyrethrum does not appear to ... the soil 24 hours after ... lication.

...ailability and Applications

...rethrum powder, as well as crude ...refined pyrethrum concentrates, ...obtained in various qualities from ...pliers in different countries. But ... world's largest producer, The ...rethrum Board of Kenya, supplies ...rethrum as a crude oleo-resin ...tract that contains 25% pyrethrins ...an odorless isoparaffinic solvent. ...e material is suitable for agricul...al sprays and mosquito coils. A ...milar, but partially refined concen...ate is also available; it can be ...ed in fly sprays and other ...secticides. A fully refined, ...olorized and deodorized pale ...tract, at 25% and 50% ...rethrins content, is available ... insecticidal aerosols and sim... preparations.

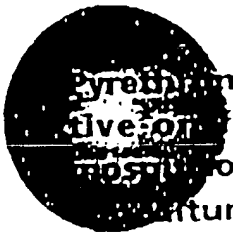
A commercial pyrethrum pow..., containing 1.3% pyrethrins, ... used for the formulation of ...secticidal dusts and mosquito ...ils. Additionally, there is avail...le a special mosquito coil pow...r containing 0.6% pyrethrins.

Pyrethrum marc is a coarse or fine ...wder which is obtained by grinding ...ied flowers after solvent extraction. ...is material can contain about 0.1% ... residual pyrethrins and may also ... used for mosquito coil manufac...re. The finely ground material has ...od burning properties with a pleas...t aroma.

Household sprays and aerosols ...ust be oil-based because pyrethrins ...e only soluble in non-polar sol...nts. Suitable solvents include var...us petroleum fractions with low ...romatics content. Odorless ...rosene or commercial iso-paraffins ...e the preferred non-polar solvents. ...dustrial sprays are usually diluted ...th a light mineral oil. Mists or fogs ...an be produced with a heavier oil ...nd in cases involving the treatment ...f foodstuffs, certain edible oils can ...e used.

Water based products are also ...vailable, but due to their water ...nsolubility, the pyrethrum extracts ...ave to be solubilized or emulsified ...th surfactants. Water-based prod...cts are becoming more popular ...ecause of legislative pressures to ...ince levels of VOCs (volatile organic ... compounds) entering the atmo...phere. There is also a continuing ... consumer demand for "safer" prod... Water-based products attack on the advantages of low odor and flammability and leave a less oily residue.

Due to the presence of ester groups in all natural pyrethrins, products cannot have high pH values. This makes the use of conventional soap-type emulsifiers inadvisable. Ethoxylated anionic and nonionic surfactants can, however, be used to produce fairly stable oil-in-water emulsions. Micro-emulsions are also used. Pyrethrins are fairly tolerant toward lower pH values, but are incompatible with metals such as lead, brass, copper, zinc and iron, particularly in the case of water-based preparations.



Pyrethrum is also effective on fleas, lice and mosquitoes, and it has agricultural applications as well.

General Household Products

When used in the home as pressure or aerosol sprays, pyrethrum-containing products are safe and effective insecticides against most types of flying insects. They are particularly effective against houseflies and mosquitoes, because of their fast knockdown and good toxicity. There is an added advantage to using pyrethrum-based products on houseflies: Pyrethrum rapidly paralyzes the insects and makes them fly toward daylight, out windows and away from food preparation or storage areas.

Aerosols and pressure sprays containing pyrethrum are also used against cockroaches, fleas, ants and similar crawling insects. An advantage of using pyrethrum-based products against cockroaches is their ability to rapidly bring cockroaches out of their daytime hiding places. This indicates product efficacy to the consumer. Pyrethrum preparations may also be used around the outside of the house and in the garden to destroy pests on flowers and vegetables. When used in or around the house, it ... [illegible] ... aquatic life.

Other Uses for Pyrethrum

Pyrethrum is also effective on fleas, lice and mosquitoes, and it has agricultural applications as well. The flea is a very adaptable parasite: both man and domesticated pets, such as cats and dogs, are suitable hosts. A flea has a four-stage life cycle, passing from egg to larva to pupa to adult, a process which takes about four weeks. After consuming blood from the host, the adult female can lay several hundred eggs in the course of a few days. The eggs fall from the host and the larvae soon hatch. Adult fleas spend most of their time on the ground or in carpets. They only attach themselves to a host for feeding. This period occupies only about 10% of their life span. The adult stage is the best time to eradicate this undesirable parasite. A liquid or powder preparation containing 0.2% of pyrethrins and 1% piperonyl butoxide is usually quite effective. The inclusion of 0.25% of a suitable insect growth regulator, such as methoprene, is beneficial because it inhibits egg hatching and larva development.

Lice are only parasitic toward mammals and their occurence in man, particularly as head lice in children, is quite socially unacceptable. Other types of body lice also exist. Lice infestation is readily transferred from one individual to another by direct contact or by the use of commonly shared articles such as combs, brushes or clothing. If left unchecked, lice infestation can reach epidemic proportions, especially in hospitals, schools or similar institutions. The development cycle of the louse is about four weeks. From the egg (called nits) stage to the adult stage, the louse passes through three nymph stages. Pyrethrum is frequently used to control lice infections. It can be incorporated in a powder, an aqueous cosmetic lotion or a shampoo.

Mosquito coils are slow burning pyrethrum containing products that create an aromatic, insecticidal smoke. These coils kill mosquitoes, houseflies and other flying insects and keep them from feeding in areas where the coils are burning. The